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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,715	08/20/2003	George V. Guittard	AR02366USA CON3	8447
27777	7590	01/26/2005		
EXAMINER				
GEORGE, KONATA M				
ART UNIT		PAPER NUMBER		
		1616		

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/645,715	GUITTARD ET AL.
	Examiner Konata M. George	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 October 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 32-48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 32-48 are pending in this application.

### ***Action Summary***

1. The objection of claims 32 and 40 as containing language that is not commonly recited is hereby withdrawn.
2. The rejection of claims 32 and 36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4 of US 5,674,895 as stated in the previous office action.
3. The rejection of claims 40 and 48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US 5,840,754 as stated in the previous office action.
4. The rejection of claims 32-39 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of US 5,912,268 as stated in the previous office action.
5. The rejection of claims 32, 36, 40 and 44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-10 and 16-21 of US 6,124,355 as stated in the previous office action.
6. The rejection of claims 40-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 5 of US 6,262,155 as stated in the previous office action.

7. The rejection of claims 32 and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 32 of copending application number 09/785,805 as stated in the previous office action.
8. The rejection of claims 32-39 under 35 U.S.C. 103(a) over Kodamma KK is being maintained for the reasons stated in the previous office action.

***Response to Arguments***

9. Applicant's arguments filed October 20, 2004 have been fully considered but they are not persuasive.

Applicant argues that the prior art reference of Kodama KK does not mention delivering the dosage form at a substantially zero order rate of release. It is the position of the examiner that the limitation of zero order rate of release is met by the prior art. The invention as claimed by applicant is a dosage form comprising 5 mg to 250 mg of oxybutynin and its pharmaceutically acceptable salt. The rate of release is a limitation that is not clearly defined in the claims. The applicant does not disclose any additional ingredients or additives that allow the dosage form to have a zero order rate of release. The composition as claimed is a specific dosage form of a drug and its salts.

***Conclusion***

10. Claims 32-48 remain rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George



SHELLEY A. DODSON  
PRIMARY EXAMINER